

JUL 27 2000

510(k) SUMMARY

K001536

**Sponsor:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, Texas 78717  
(512) 432-9900

**Contact Person:** Mitchell Dhority, RAC  
Manager, Regulatory & Clinical Affairs

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR 888.3358

**Common/Usual Name:** Total Hip Prosthesis, Semi-constrained

**Trade/Proprietary Name:** Inter-Op Metasul Hooded and Protrusio Inserts

**PRODUCT DESCRIPTION**

Inter-Op Metasul Hooded Insert

The Inter-Op Metasul Hooded Insert is a hemispherical polyethylene component manufactured from UHMWPE (ASTM F648). The polyethylene outer diameter of the insert is machined with locking features that mate with one of the previously cleared Inter-Op metallic acetabular shells. The face of the polyethylene outer diameter incorporates a 20° overhang of material extending superiorly from the center line. The hood feature is used to provide additional resistance to subluxation and instability.

Inter-Op Metasul Protrusio Insert

The Inter-Op Metasul Protrusio Insert incorporates all of the features described above for the Inter-Op Metasul Hooded Insert. Additionally, the Inter-Op Metasul Protrusio insert is designed such that the polyethylene outer diameter provides an added offset in the center of rotation of approximately 5.5mm (as compared to the previously cleared Inter-Op Metasul Insert). This feature is used to lateralize the femur, thus restoring anatomic tension on soft tissue. It is intended to compensate for a situation where there is medial displacement of the acetabular shell by allowing for normal positioning of the femoral head.

Both the Inter-Op Metasul Hooded and Protrusio Insert feature the metallic Metasul inlay in the inner diameter of the insert. The metal inlay is manufactured from Protasul®-21WF, a wrought forged CoCrMo alloy (ISO 5832-4, ISO 5832-12), and forms the articulating surface. This inlay is polished to a mirror-finish and hot-pressed into the UHMWPE backing. Just prior to hot-pressing, two Protasul-10 (CoCr alloy, ASTM F562) pins may be press fit into the design of the inlay to help provide added rotational stability. As a result of the strictly controlled tolerances of the inlay and in order to recognize the beneficial wear properties associated with this component, this insert is designed for use only with previously cleared Metasul head components.

These insert components are available with outside diameters of 49mm to 81mm (in 2mm increments) with an inner diameter of 28mm.

## **INTENDED USE / DIAGNOSTIC INDICATIONS**

The Inter-Op Metasul Hooded and Protrusio Inserts are intended for use with the Inter-Op Acetabular Shells and Metasul femoral heads in total hip arthroplasty for treatment of the following:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed arthroplasty.

## **SUBSTANTIAL EQUIVALENCE**

Substantial equivalence is based on comparison to the previously cleared, commercially available Inter-Op Metasul Inserts and Inter-Op Hooded and Protrusio Inserts. The fundamental scientific technologies incorporated into these products has not changed in the Inter-Op Metasul Hooded and Protrusio Inserts. Based on similarities in design, materials, sterilization, method of manufacture, intended use and indications for use, we believe the Inter-Op Metasul Hooded and Protrusio Inserts are substantially equivalent to the previously cleared Inter-Op Metasul Inserts and Inter-Op Hooded and Protrusio Inserts.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 27 2000**

Mr. Mitchell A. Dhority, RAC  
Manager, Regulatory & Clinical Affairs  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

Re: K001536

Trade Name: Inter-Op™ Metasul® Hooded and Protrusio Acetabular Inserts  
Regulatory Class: III  
Product Code: KWA  
Dated: May 16, 2000  
Received: May 17, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

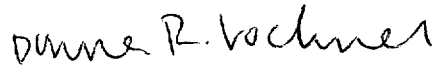
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.


This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K001536

Device Name: Inter-Op Metasul Hooded and Protrusio Inserts

### Indications for Use:

The Inter-Op Metasul Hooded and Protrusio Inserts are intended for use in cases of total hip replacement for treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, post traumatic arthritis or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.
3. Revision of previously failed hip arthroplasty.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dr. R. W. W. W.

(Division Signature)

Division of General Restorative Devices

510(k) Number: K001536

Prescription Use

X

OR

Over-the Counter Use

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(Optional Format 1-2-96)